OCT 2 0 2000

510(k) Summary

K000246

RadioCameras™ Extracranial System

Submitted on January 7, 2000

I. **Submitter Information:**

Contact: Roger N. White
Group Director, Quality Systems and Regulatory Affairs
Surgical Navigation Technologies
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(303) 439-9709
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II. **Trade name:** RadioCameras™ Extracranial System
Common or usual name: Image Processing System
Classification name: Image Processing System (per 21 CFR section 892.2050)

III. The above device is substantially equivalent to the RadioCameras Localization and Positioning System (K981346 and K980750) and the Nomos BAT™ System ((K981424). The substantial equivalence was established by comparison of functions and features.

IV. This submission describes a system that is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures. The RadioCameras™ System uses optical tracking of infrared markers as the method of locating the position of the patient. The RadioCameras™ System consists of a high resolution linear CCD camera array, computer workstation, an optical positioner, and an optical calibration jig. Optionally, the system interfaces to an ultrasound system so that the treatment site can be adjusted for soft tissue shifts.

V. The RadioCameras™ System is indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on cranial or extracranial lesions. The RadioCameras™ System provides precise positioning of the treatment target at the Linear Accelerator's isocenter.

VI. The technological characteristics are the same as or similar to those found with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2000

Ronald K. Smith
Director
Quality System & Regulatory Affairs
Medtronic Surgical Navigation Technologies
Coal Creek Corporate Center One
826 Coal Creek Circle
Louisville, CO 80027

Re: K000246
RadioCameras™ Extracranial System
Dated: September 1, 2000
Received: September 5, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K000246

Device Name: RadioCameras™ System

Indications For Use:

The RadioCameras™ System is indicated for use with a Linear Accelerator to perform Stereotactic Radiosurgery or Radiotherapy on cranial or extracranial lesions. The RadioCameras™ System provides precise positioning of the treatment target at the Linear Accelerator's isocenter.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use Y OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000246